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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,458	11/28/2003	Leslie William Organ	BEW-005RCE	9862

959 7590 11/28/2008

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
11/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,458	ORGAN ET AL.	
	Examiner	Art Unit	
	RENE TOWA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-14 and 16-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-14 and 16-24* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed August 18, 2008. Claims 1-2, 4-14 & 16-24 are pending. Claims 1-2, 4, 6, 13, 16 & 18 have been amended.

Claim Objections

2. The objections are withdrawn due to amendments.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. **Claims 1-2, 4-5, 7-11, 13-14, 16-17 & 19-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ (US 6,122,544) in view of Kuenecke et al. (US 5,196,008), Newton et al. (US 4,416,276) and further in view of Netherly et al. (US 6,171,304).

In regards to **claims 1 & 13**, Organ discloses a system for diagnosing the possibility of disease in a body part, the method comprising

providing an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part;

making an electrode assessment measurement with the electrode array;

making a diagnosis measurement with the electrode array;

obtaining an electrical property of the body part based on the diagnosis measurement; and

diagnosing the possibility of disease based on the electrical property of the body part (see fig. 5; column 3/lines 29-44; columns 4-11, lines 14-46).

In regards to **claims 2 & 14**, Organ discloses a system wherein the plurality of electrodes includes a current injection electrode pair and an associated voltage measurement electrode pair that are applied to the body part (see column 4, lines 35-39).

In regards to **claim 7**, Organ teaches a system wherein the plurality of electrodes includes n_{cl} current injection electrode pairs, and n_{cl} associated voltage measurement electrode pairs, where n_{cl} is an integer greater than zero (see Column 4, lines 35-38).

In regards to **claim 8**, Organ discloses a system wherein the step of making a diagnosis measurement includes applying the n_{cl} current injection electrode pairs on the body part; and applying the n_{cl} voltage measurement electrode pairs on the body part (see Column 4, lines 35-59).

In regards to **claims 9-11 & 19-23**, Organ discloses a system wherein the step of making a diagnosis measurement further includes

injecting a first current between a first pair of the n_{cl} current injection electrode pairs;

measuring the resultant voltage difference V.sub.1.sup.M between the voltage measurement electrode pair associated with the first current injection electrode pair; and repeating the preceding two steps of injecting and measuring with the other electrode pairs until all n_{cl} voltage differences, $\{V_1^M, V_2^M, \ldots V_{ncl}^M\}$ are obtained; wherein the electrical property is impedance; wherein the step of obtaining includes using the n_{cl} voltage differences to obtain associated measured impedances, $\{Z_1^M, Z_2^M, \ldots, Z_{ncl}^M\}$, where Z_j^M is the measured impedance between the voltage electrodes associated with

the jth current injection electrode pair (see Columns 6-8, lines 5-14; see columns 6-11, lines 5-53).

Organ discloses a system, as described above, that fails to explicitly teach an electrode assessment measurement that includes a bipolar electrode assessment measurement that compares the measurement to anthropometric data indicative of adequate coupling. Organ further discloses a system, as described above, that fails to explicitly teach measuring a phase to determine suitable coupling of the electrodes to the body part.

However, **Kuenecke et al.** disclose a system comprising:

providing an electrode array 1 (see fig. 1; col. 3, lines 22-31);

making a bipolar electrode assessment measurement with the electrode array 1 by utilizing one current injection electrode and one voltage measurement electrode (see col. 3, lines 40-50 & 58-68);

determining whether the plurality of electrodes (2-5) are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement (see col. 4, lines 1-6 & 46-52; see abstract).

Moreover, **Newton et al.** disclose a system comprising:

coupling electrodes (20, 22) to a body part;

providing anthropometric data (i.e. an impedance value in a range of 20 to 144 ohms) indicative of adequate coupling between the electrodes (20, 22) and the body part (see col. 3, lines 33-62);

making a bipolar electrode assessment measurement by utilizing one current injection electrode 20 and one voltage measurement electrode 22 (see col. 3, lines 19-32);

determining whether the plurality of electrodes are suitably coupled to the body part based on a comparison of the bipolar electrode assessment measurement with anthropometric data (i.e. 20 to 144 ohms) indicative of adequate coupling between the electrodes and the body part (see figs. 1 & 4; col. 3, lines 33-62).

Netherly et al. disclose a system for determining whether the plurality of electrodes are suitably coupled to a patient body part through computation of a phase angle of the impedance (see col. 4, lines 32-36 & 45-50; col. 10, lines 43-49; see claims 1-4 of Netherly et al.).

*In regards to **claims 1 & 13**, although Organ stresses the importance of good electrode/body contact (see col. 4, lines 49-54; col. 5, lines 54-58), Organ fails to teach an electrode assessment measurement to determine whether the electrodes are suitably coupled to a body part; however since both Organ and Kuenecke et al. teach systems comprising electrodes that are in contact with and apply electrical current through a body part, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the system of Organ to include a bipolar electrode assessment measurement as taught by Kuenecke et al. in order to determine whether the electrodes are suitably coupled to the body part; for example, poor electrode/body contact quality can lead to inconsistencies in measurement and diagnosis.*

Similarly, although Organ teaches comparing the body impedances to anthropometric data indicative of disease state (see col. 3, lines 36-46; col. 9, lines 37-43; col. 10, lines 13-23 & 44-51; col. 11, lines 33-46), Organ fails to explicitly teach comparing the electrode assessment measurements to anthropometric data indicative of adequate coupling between the electrodes and the body part; however, since Newton et al. teach a system wherein the electrode assessment measurement is compared to anthropometric data in order to bind the electrode/body contact impedance between a lower and an upper limit threshold so as to thereby detect tenting, incorrect application site, gel drying and the hazards of applying the electrode on a surface other than the patient (see col. 3, lines 33-62), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Organ as modified by Kuenecke et al., above, with an anthropometric data comparison as taught by Newton et al. in order to bind the electrode/body contact impedance between a lower and an upper limit threshold so as to thereby detect tenting, incorrect application site, gel drying and the hazards of applying the electrode a surface other than the patient.

In regards to ***claims 4-5 & 16-17****, it is known that impedance includes both a magnitude and phase component (see col. 7, lines 13 to col. 8, line 3 of US 5,372,141). As such, Kuenecke et al. teach an electrode/body contact system that measures both the magnitude and phase of the electrode/body contact impedance (see col. 4, lines 46-52); Newton et al. disclose a method wherein electrode/body contact assessment is established by only monitoring the magnitude of the electrode/contact impedance with respect to anthropometric data (20 to 144 ohms). Since Netherly et al. teach that*

electrode/body contact assessment can also be established by only measuring the phase of the electrode/body contact impedance rather than both the magnitude and phase or the magnitude alone, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Organ as modified by Kuenecke et al. and Newton et al., above, with a phase determining step as taught by Netherly et al. in order to easily determine the quality of the electrode/body contact by measuring a change in phase angle. Moreover, since it is known that impedance only includes two components such as a magnitude and phase component (see col. 7, lines 13 to col. 8, line 3 of US 5,372,141); and since Kuenecke et al. teach that it is known to perform a bipolar electrode assessment from an electrode array to determine electrode-tissue contact while Newton teaches that it is known to perform a bipolar electrode assessment by comparing the electrode impedance with an anthropometric data to determine the state of electrode-tissue contact; whereas, Netherly et al. teach that it is known to establish electrode-tissue contact using the phase angle only (as opposed to the impedance as a whole which includes a magnitude and a phase, or the impedance magnitude alone), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Organ as modified by Kuenecke et al. and Newton et al., above, with a phase determining step as claimed since it is known that impedance only includes two components such as magnitude and phase; for example, if one were to perform a known impedance measurement comparison with anthropometric data, it is at least an obvious expedient that one would be inclined to perform an impedance magnitude

measurement comparison with anthropometric data or an impedance phase measurement comparison with anthropometric data (i.e. there is only so many ways to compare the impedance itself or the components thereof with anthropometric data) to determine the state of electrode-tissue contact.

5. **Claims 12 & 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Kuenecke et al. ('008), Newton et al. ('276), Netherly et al. ('304), and further in view of Dempsey et al (US 5,419,337).

Organ as modified by Kuenecke et al., Newton et al.and Netherly ('304) discloses a system, as described above, that fails to explicitly teach a system comprising a GUI.

However, **Dempsey et al.** discloses a graphical user interface that indicates a status of the coupling between a plurality of electrodes and the body part (see col. 5, lines 13-29).

Since both Organ and Dempsey et al. teach systems comprising electrodes that are in contact with a body part, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Organ as modified by Kuenecke et al., Newton et al.and Netherly ('304) to include a user interface, as taught by Dempsey et al, in order to interpret the quality of the signals of each electrode, for either gain selection or determining which electrodes may have poor skin contact.

6. **Claims 6 & 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ ('544) in view of Kuenecke et al. ('008), Newton et al. ('276), Netherly et al. ('304), and further in view of Netherly et al. (US 6,007,532).

Organ as modified by Kuenecke et al., Newton et al.and Netherly ('304) discloses a system, as described above, that fails to explicitly teach measuring a phase at a plurality of frequencies to determine suitable coupling of the electrodes to the body part.

However, **Netherly et al. ('532)** disclose a system for determining whether the plurality of electrodes are suitably coupled to a patient body part through computation of a magnitude and/or phase angle of the impedance; wherein the contact impedance at a plurality of frequencies serves as a means for determining the quality of electrode/body contact (see fig. 3; col. 3, lines 31-56; col. 4, lines 26-37 & 53-57; col. 5, lines 29-40).

Since Newton et al. disclose a method wherein electrode/body contact assessment is established by only monitoring the magnitude of the electrode/contact impedance with respect to anthropometric data (20 to 144 ohms) and since Netherly et al.('532) teach that electrode/body contact assessment can also be established by measuring the electrode/body contact impedance at a plurality of frequencies; it is known that impedance includes both a magnitude and phase component. Kuenecke et al. teach an electrode/body contact system that measures both the magnitude and phase of the electrode/body contact impedance (see col. 4, lines 46-52); as such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Organ as modified by Kuenecke et al., Newton et al. and Netherly ('304) above, with an impedance at a plurality of frequencies as taught by Netherly et al.('532) in order to determine the quality of the electrode/body contact. Moreover, the Applicant has not disclosed that determining an impedance by

way of a phase determination provides an advantage, is used for a particular purpose, or solves a stated problem over the prior art.

Response to Arguments

7. Applicant's arguments filed August 18, 2008 have been fully considered but they are not persuasive. Applicant contends that the combination of Organ, Kuenecke and Newton teaches or suggests the step of determining whether the plurality of electrodes are suitably coupled to the body part based on a comparison of hte bipolar electrode phase measurement to the anthropometric data. This argument has been considered but has not been deemed persuasive.

In response to the Applicant's argument, the Examiner respectfully traverses. First, the Examiner notes that, although the Applicant purports to argue against the combination as a whole, the Applicant's arguments are really based on a piecemeal analysis. For example, the Applicant essentially restates what the Examiner has admitted either directly or by inference with regard to the Organ, Kuenecke et al., and Newton references. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As such, the Applicant's reply has failed to address the rejection as a whole. For example, the Examiner has asserted that while Organ lacks a teaching of a bipolar electrode phase measurement that compares the bipolar measurement to anthropometric data indicative of adequate tissue coupling, Kuenecke

et al. teach that it is known to perform a bipolar electrode assessment from an electrode array to determine electrode-tissue contact; Newton teaches that it is known to perform a bipolar electrode assessment by comparing the electrode impedance with an anthropometric data; whereas, Netherly et al. teach that it is known to establish electrode-tissue contact using the phase angle only (as opposed to the impedance as a whole which includes a magnitude and a phase, or the impedance magnitude alone); as such, the Examiner surmised that it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to perform an bipolar phase measurement assessment from an electrode array in order to easily determine the state of electrode-tissue contact by measuring the change in phase angle with respect to anthropometric data. Ostensibly, the Applicant does not seem to dispute this assertion.

In view of the foregoing, the rejections over at least one of Organ, Kuenecke et al., and Newton are maintained.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information in regards to the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736